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Remarks

Claims 1 (Amended), 2-9, 13, 39-41, 43, 44 (Amended), 45, 46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 are pending. Claims 10-12, 14-38, 42, 47, 48, 51, 52, 55-59, 62-71, 76, 78-80 and 86-101 were previously cancelled. Applicants respectfully request reconsideration of this application in view of the claim amendments and the following remarks.

Amendments to the Specification

Two paragraphs of the specification were amended to capitalize the brand name TRITON. The Abstract was also amended to conform with current PTO practice. No new matter has been added by these amendments.

Amendments to the Claims

Claim 1 has been amended to recite that the microchannels are adapted to draw a fluid sample into the acquisitions zone through openings in the microchannels, and to provide fluid flow of the fluid sample from the acquisition zone to the detection zone by spontaneous fluid transport. This amendment is fully supported by the specification at, for example, page 18, lines 15-23.

Rejection Under 35 U.S.C. § 112, second paragraph

All of the pending claims were rejected under section 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action stated that the claim language "film," "uninterrupted fluid flow of a fluid sample," and "spontaneous," as used in claim 1 is indefinite.

Regarding the term "film," the Office Action stated that the specification defines "film" as being "generally flexible", however, the metes and bounds of the phrase "generally flexible" is not clear. For example, the Office Action stated that "generally" could be equivalent to the word "about," which would be inclusive of inflexible films. The Office

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Action also stated that "generally" could be a limitation on all films, and if so, the extent of flexibility of the claimed film is vague.

It is well established that a claim term is not indefinite when it serves to reasonably describe the subject matter so that its scope would be understood by persons in the field of the invention and to distinguish the claimed subject matter from the prior art. *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). Thus, the issue under Section 112 is not whether the claim term has a fixed meaning as used in the claims or specification, but rather, how the phrase would be understood by persons of skill in the art. *Id.* Furthermore, the mere fact that there may be divergent opinions as to the meaning of the word does not render the scope of the claim invalid. *Id.* It is respectfully submitted that persons of ordinary skill in the art would understand that the phrase "generally flexible," as it defines the term "film," refers to films having at least some flexibility, as opposed to a rigid structure, which lacks flexibility. Thus, the claim recitation of "film" is not indefinite and Applicants respectfully request withdrawal of this rejection.

The Office Action stated that the scope of the phrase "uninterrupted fluid flow of a fluid sample," is unclear because it could mean that the sample flows without interruption in the sample per se, or alternatively, that no valves control fluid flow. Claim 1 has been amended to recite that the microchannels are adapted to provide fluid flow between the acquisition and detection zones by spontaneous fluid transport. Applicants respectfully submit that this claim amendment renders this rejection moot.

Regarding the phrase, "by spontaneous fluid transport," the Office Action stated that the term "spontaneous" is not defined in the specification, however, one reasonable dictionary definition defines the term "spontaneous" as "occurring without external cause." The Office Action further stated that this definition could be interpreted in the context of the claimed invention as meaning a cause external to the sample, or alternatively, a cause external to the detection article.

Claim 1 has been amended to recite that the microchannels are adapted to draw fluid into the acquisition zone, and to provide fluid flow between the acquisition and detection zones by spontaneous fluid transport. Applicants respectfully submit that the term

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"spontaneous" as it refers to fluid transport is clearly defined in the specification. For example, page 18, lines 15-23 of the specification report that two factors that influence the ability of a fluid control film to spontaneously transport fluids are (i) the structure or topography of the surface (e.g., capillarity, shape of the channels), and (ii) the nature of the film surface (e.g. surface energy). The specification then reports how the contact angle of the fluid influences spontaneous fluid transport, and how the control film material may be adjusted or modified to enhance spontaneous fluid transport, for example, by adjusting microchannel geometry and/or by affecting the hydrophilic characteristics of the film with a surfactant or other coating material. Thus, one of skill in the art would interpret the phrase "spontaneous fluid transport" to mean fluid transport caused by the structure or topography of the film surface and/or by the nature of the film surface. Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. 102

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81 and 83-85 were rejected under section 102(e)(2) as being anticipated by U.S. Patent No. 6,416,642 to Alajoki et al. The Office Action stated that Alajoki et al. reports flexible microfluidic devices including the claimed microchannels. The Office Action further stated that the reported devices utilize continuous flow, as well as wicking and other fluid transport practices.

Claim 1 has been amended to recite that the microchannels are adapted to draw fluid into the acquisition zone, and to provide fluid flow between the acquisition and detection zones by spontaneous fluid transport. Applicants respectfully submit that the devices reported in Alajoki et al. do not provide for spontaneous fluid transport between an acquisition zone and a detection zone. Instead, fluid flow is regulated by (1) placing an absorbent material downstream from the fluid, and/or (2) electrokinetic or pressure based injection or withdrawal of materials downstream from the fluid (Col. 2, lines 24-34). Thus, Alajoki et al. does not report a device capable of spontaneous fluid transport because the device requires the application of forces external to the film topography and/or surface. Applicants respectfully request withdrawal of this rejection.

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Claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81 and 83-85 were rejected under 35 U.S.C. 102(b) and (e)(2) as being anticipated by U.S. Patent No. 4,673,657 to Christian. The Office Action stated that Christian reports an assay card with channels and chambers interconnected with flexible elements for a variety of assays.

Claim 1 has been amended to recite that the microchannels are adapted to draw fluid into the acquisition zone, and to provide fluid flow between the acquisition and detection zones by spontaneous fluid transport. Applicants respectfully submit that the devices reported in Christian do not provide for spontaneous fluid transport.

Figures 12-14 of Christian illustrate an exemplary assay card. The card has a series of closed channels 122, 123, 124 and 125. A microassay rod 10 is positioned in channel 122. Channels 123, 124 and 125 include treatment solutions such as reagents and wash solutions. The sample is inserted into channel 122 through opening 126. After the card is incubated, it is passed under a solenoid operated roller 130 which squeezes the sample out of channel 122 and through opening 126. The card is then placed under roller 130 in a series of steps such that the contents of channels 123, 124 and 125 are forced into channel 122.

As is evident from this description, the assay card does not provide for spontaneous fluid transport of the sample from an acquisition zone to a detection zone. Instead, mechanical forces are required to transport fluids. Indeed, if the system provided for spontaneous fluid transport, the reagents would undesirably come into contact with the sample during the incubation period. Thus, the card does not provide spontaneously fluid transport of the sample from an acquisition zone to a detection zone. Applicants respectfully request withdrawal of this rejection.

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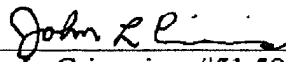
CONCLUSION

The pending claims are in condition for allowance. Applicants respectfully request a notice to that effect. If there are any remaining questions, the Examiner is encouraged to contact the undersigned at the number listed below.

Respectfully Submitted,

RAYMOND P. JOHNSTON et al.

By:


John L. Crimmins, #51,589
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
612/766-7749

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